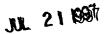
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75-111

BIOEQUIVALENCE

Ipratropium bromide 0.02% Inhalation solution NDA #75-111 Reviewer: J. Lee 75111W.497



Alpharma Baltimore, MD Submission date: April 11, 1997

Review of a Request for Waiver

The sponsor has submitted an application for ipratropium bromide 0.02% inhalation solution and is requesting a waiver from in-vivo bioequivalence testing for their test product under 21 CFR 320.22 (b)(3). The sponsor has provided a comparison (attached) between their test product and Atrovent® 0.02% inhalation solution (Boehringer Ingelheim) with regard to conditions of use, active ingredient, dosage form, route of administration, and strength.

The drug product is intended for inhalation administration.

A qualitative/quantitative formulation comparison is provided below:

Alpharma Atrovent per 2.5 ml per 2.5 ml

Ipratropium bromide Sodium chloride HCl Water for injection

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Comment:

1. The test and reference products are qualitative and quantitively the same within the guidelines of 'sameness' in OGD's Inactive Ingredients Guide.

Recommendation:

1. The Division of Bioequivalence agrees that the information submitted by the sponsor demonstrates that ipratropium bromide 0.02% inhalation solution falls under 21 CFR 320.22 (b)(3) of Bioavailability/Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of an in-vivo bioavailability study be

Section IV

Information demonstrating that the proposed product is the same as the listed product.

LISTED DRUG PROPOSED DRUG

Atrovent® 0.02% Ipratropium Bromide

Inhalation Solution Inhalation Solution, 0.02%

Boehringer Ingelheim Alpharma

Conditions of use: Indicated as a bronchodilator for maintenance treatment of

bronchospasm associated with chronic obstructive pulmonary disease,

including chronic bronchitis and emphysema.

Active Ingredient: ipratropium bromide ipratropium bromide

Dosage Form: solution solution

Route of Administration: inhalation inhalation

Strength: 0.02% 0.02%